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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,644	04/12/2004	Stephen R. Wilson	4451.002200/RFE	1907
23720 7590 10/30/2007 WILLIAMS, MORGAN & AMERSON 10333 RICHMOND, SUITE 1100 HOUSTON, TX 77042			EXAMINER PURDY, KYLE A	
			ART UNIT 4173	PAPER NUMBER
			MAIL DATE 10/30/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/822,644

Applicant(s)

WILSON ET AL.

Examiner

Kyle A. Purdy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 5-13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 13-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3</u> sheets. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election Acknowledged

1. Applicants' election without traverse the invention of Group I encompassing claims 1-15 received on September 28, 2007 is acknowledged. The restriction is made final without traverse. Therefore, the restriction requirement is deemed to be proper and made final.

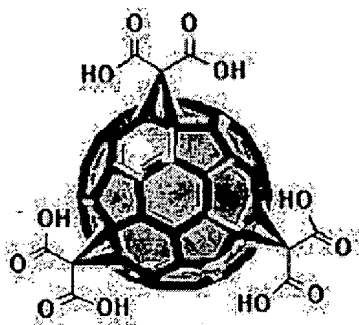
2. Claims 5-12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. The elected species was specifically the species of fullerene wherein the compound had the generic formula $C_{60}(>C(COOH)_2)_3$, wherein the three $>C(COOH)_2$ moieties are in the C3 conformation. Claims 5-12 do not read on the elected species. For example claim 5 recites a substituted fullerene which comprises C_{60} and 2 $>CX^1X^2$ groups. The elected species requires three and thus does not read on the elected species.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4 and 13-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the compound



, but does not reasonably provide enablement for all substituted fullerenes listed in groups (i) – (iv). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

5. There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court *In re Wands* (8 USPQ2d 1400 (FACF 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the state of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

6. The claims of the instant invention are drawn to a method of ameliorating a dermatological condition such as acne, psoriasis and aging in the skin of a mammal comprising administering a substituted fullerene. These claims are quite broad and there is insufficient evidence to support the claims that the instant composition is actually capable of ameliorating such dermatological conditions.

7. The skilled artisan would view the treatment and amelioration of said dermatological conditions as unpredictable and dependent upon many complex chemical and biological factors.

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The current state of the art exemplifies as much. Weinert et al. (J. Applied Physiology, 2003, 95, 1706-1716) states that the currently many theories which may adequately describe some or all features of the normal aging process which include molecular, evolutionary, and cellular theories. It is stated that the ultimate causes of aging is complex and remains largely unknown (see page 1713, column 2, second paragraph).

8. Most importantly, in the instant case, sufficient representative data is not present to support the claim that the method of using substituted fullerenes to ameliorate a skin condition. It is noted that Applicant defines ameliorate to encompass prevention and treatment of a skin condition; neither of which is supported by the disclosure. The application puts forth Fig. 1 and Fig. 11A-11H (Example 1 and Example 2, respectively) as evidence to support the instant claims. However, the data provided is insufficient because it does not demonstrate the ability to treat or prevent said skin conditions at all. It is impossible to determine anything from Fig. 1 as the figure is blacked out and the data present in Fig. 11A-11H is drawn to a chemical assay involving free radical inactivation that has nothing to do with the amelioration of a skin condition. Assuming that the image of Fig. 1 was clear, the mere presentation of only one treatment result would not lend any support to the efficacy of the method. Specific and multiple working examples are critical in cases involving unpredictable and underdeveloped art. See MPEP 2164. The evidence provided is not commensurate in scope with the claimed invention and does not critically demonstrate that the claimed properties of the claimed method.

9. Therefore, in view of the Wands factors, i.e. the amount of guidance and data present, absence of working examples and the unpredictability of the art as discussed above, to practice

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the claimed invention herein, a person in the art would have to engage in undue experimentation with no assurance of success.

Claim Rejections - 35 USC § 102

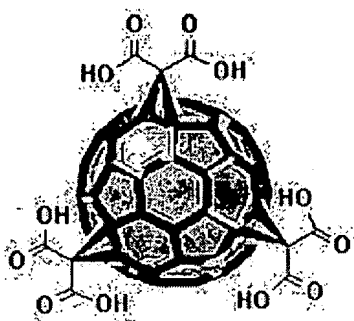
10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-4 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Fumelli et al. (Society for Investigative Dermatology, 2000, 115:5, 835-841).

12. The claims of the instant application are drawn to a method for ameliorating a dermatological skin condition such as aging and psoriasis in the skin of a mammal with a substituted fullerene wherein the fullerene comprises 60 to 70 carbons and is in the C₃ orientation. The fullerene of the composition is of the following structure



13. Fumelli et al. ('Fumelli) is drawn to the composition and method of using carboxyfullerenes (CF) having the above structure for the protection of human keratinocytes from ultraviolet-B (UV-B) induced apoptosis. UV radiation is a major source of biological

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damage to the skin as UV radiation is believed to create oxygen free-radicals (see page 835, column 2, second paragraph). Fumelli discloses that a method of using a C3 form of CF, specifically that of e,e,e-C₆₃(COOH)₆ as being useful in protection of human keratinocytes (see page 836, column 1, Figure 1). On page 838, column 2 under 'CF protect human keratinocytes from apoptosis' it is stated it is stated that a significant and dose-dependent reduction of apoptotic keratinocytes in CF-pretreated cells compared to cells treated with diluent was observed. The data presented in the paper indicated that CF protects keratinocytes from UV-B induced apoptosis via an antioxidant mechanism involving mitochondria and the generation of reactive oxygen species (see page 840, column 2, second paragraph).

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Ardin Marschel and Cecilia Tsang, can be reached on 571-272-0718 or 571-272-0562, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

16. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

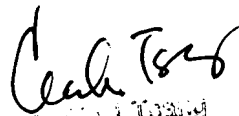
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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle A. Purdy/

Examiner, Art Unit 4173


Charles Tsang
Senior Patent Examiner
Technology Center 1600